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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,384	06/01/2001	Derek J. Hei	282172000810	5308

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EXAMINER	
MILLER, MARINA I	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 01/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/872,384	HEI, DEREK J.	
	Examiner	Art Unit	
	Marina Miller	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-25* is/are pending in the application.

4a) Of the above claim(s) *19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-18 and 20-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/7/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' submission filed on 10/25/2005 is acknowledged. Claims 1-3 and 5-25 are pending. Claim 4 is cancelled.

Claim 19 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claims.

Claims 1-3, 5-18, and 20-25 presently are under examination.

Applicants' arguments have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are applied.

Information Disclosure Statement

The Information Disclosure Statements (IDS) filed 11/07/2003 has been considered in part. Examiner appreciates applicant's apprising her of copending sister application listed on the IDS. References crossed out on the IDS filed 11/7/2005 have not been considered because an original application or a copy of an office action from a copending application which has not yet matured into an issued patent or otherwise become publicly available is not a proper document to be listed on PTO 1449 under 37 CFR 1.98(a).

Claim Objections

Claim 13 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 13 depends from claim 8 and recites the limitation "wherein

said resin is not prewetted." Claim 8 recites contacting biological fluid with a resin that is capable of removing psoralen without prewetting with a wetting agent. Thus, claim 13 does not further limit claim 8.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 5-6, 8-11, 13-14, 16-18, 20-23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley, U.S. Patent 6,319,662, in view of Davankov, U.S. Patent 3,729,457.

Applicants argue that Davankov teaches that "a rigid polymer may swell" (p. 9 of the applicants' answer). Applicants refer to the previously submitted publication by Davankov for the illustration of their argument. Applicants further argue that one of ordinary skill "would not conclude from Davankov *et al.*'s U.S. Pat. No. 3,729,459 that a rigid hypercrosslinked polymer would not swell or that this polymer would not require prewetting." (p. 11 of the answer). Applicants also argue that there is no motivation to combine Foley with Davankov. Applicants' arguments have been considered, but are found not persuasive.

The instant claims are rejected under 35 U.S.C. 103(a) over a combination of references. Foley discloses various resin materials used for the removal of psoralen, *e.g.*, charcoal, an ion exchange resin, and biobead (*e.g.*, Macro-Prep t-butyl HIC) (col. 5, lines 10-18 and col. 6, lines 61-63). Foley does not disclose that his resins have to be pre-wetted. In fact, Foley discloses at

least one resin (*e.g.*, charcoal) that does not require prewetting for the operation. Thus, Foley does disclose resin that does not require prewetting.

Davankov is relied upon for teaching a hypercrosslinked resin for ion-exchange chromatography. The fact that Dovankov's rigid micropopous structures may swell does not make "swelling" a requirement for the operation of Davankov's resin. Further, Davankov's article relied upon by applicants in the arguments discloses a crosslinked resin that has no ability to swell (p. 10 of the applicants' answer, p. 34 of Davankov's publication). Thus, Davankov does not require resin to be prewetted.

Motivation to combine references was provided in the previous office action and is reiterated below:

"It would have been obvious to one skilled in the art at the time of the invention to modify the method of Foley to use hypercrosslinked resin for an ion-exchange chromatography, such as taught by Davankov, where the motivation would have been to improve penetration of ions through the whole volume of an ionite granulate, to provide a mechanically strong macronet polystyrene structure with chemically stable bridges, and to improve exchange capacity, osmotic stability, and kinetic characteristics, as taught by Davankov, col. 2-3."

Claims 7 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley, U.S. Patent 6,319,662, in view of Davankov, U.S. Patent 3,729,457, as applied to claims 1-6, 8-11, 13-14, 16-18, 20-23, and 25 above, and in view of Wollowitz, U.S. Patent 5,593,823.

Applicants do not specifically address this rejection over the combination of the references. The examiner maintains that Foley and Davankov disclose the method of claims 1-3,

5-6, 8-11, 13-14, 16-18, 20-23, and 25. For the reasons stated above and in the previous office action, the rejection of claims 7 and 15 is maintained.

Claims 12 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley, U.S. Patent 6,319,662, in view of Davankov, U.S. Patent 3,729,457, as applied to claims 1-3, 5-6, 8-11, 14, 16-18, 20-23, and 25 above, and in view of Hearst, U.S. Patent 4,196,281.

Applicants do not specifically address this rejection over the combination of the references. The examiner maintains that Foley and Davankov disclose the method of claims 1-3, 5-6, 8-11, 13-14, 16-18, 20-23, and 25. For the reasons stated above and in the previous office action, the rejection of claims 12 and 24 is maintained.

Double Patenting

The instant claims were provisionally rejected under the judicially created doctrine of double patenting over various claims of copending application 10/051,976. As necessitated by amendment, the following new rejection is applied.

Grouped claims (8, 13, and 16), (10 and 17), (11 and 17), 12, (14 and 18), and 15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 16, claim 16 in view of claim 13, claim 16 in view of claim 14, claim 16 in view of claim 15, claim 16 in view of claim 19, and claim 16 in view of claim 20, respectively, of copending Application 10/051,976 ("App. '976").

Instant claim 8 is directed to a method for removing free psoralen from a biological fluid wherein psoralen was exposed to light comprising contacting the biological fluid with a

hypercrosslinked resin capable of removing free psoralen without prewetting and removing free psoralen from the biological fluid. Claims 10-18 further limit claim 8.

Claim 16 of App. '976 depends from claims 10 and 12. Claim 10 of App. '976 is directed to a method for removing free psoralen from a blood product after psoralen was exposed to light comprising contacting a blood product with a resin of porous structure capable of removing free psoralen and removing free psoralen from the blood product. Claims 12 and 16 of App. '976 further limit claim 10 to a hypercrosslinked polyaromatic resin and a non-prewetted resin similar to that recited in instant claims 8, 13, and 16. Claims 13-15, 19, and 20 of App. '976 recite the same limitation as instant claims (10 and 17), (11 and 17), 12, (14 and 18), and 15, respectively.

It would have been obvious to one skilled in the art at the time of the instant invention to modify the method of claim 16 of Appl. '976 to remove psoralen from plasma and platelets containing phosphate, such as recited in claims 13-15 of App. '976, where the motivation would have been to use a pathogen free blood product for injecting it back to patients without side effects that may be caused by psoralen. It would have been obvious to one skilled in the art at the time of the instant invention to modify the method of claim 16 of Appl. '976 to use specific known psoralen compounds, such as recited in claims 19 and 20 of App. '976.

Claims 9, 19-20, and 23-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11, 23-24, and 27-28, respectively, of copending Application 10/051,976 ("App. '976"), in view of claims 12 and 16 of App. '976.

The instant claims are directed to a method for removing psoralen from a biological fluid comprising blood and blood products and a biological fluid formed by the method.

The claims of App. '976 are directed to a method for removing psoralen from a blood product and a blood product formed by the method similar to that of the instant invention.

Claims 11, 23-24, and 27-28 of App. '976 do not recite hypercrosslinked resin or prewetted resin.

Claim 12 of App. '976 recites hypercrosslinked resin. Claim 16 recites resin, which is not prewetted.

It would have been obvious to one skilled in the art at the time of the invention to modify the method of claims 11, 23-24, and 27-28 of Appl. '976 to use hypercrosslinked not prewetted resin, such as recited in claims 12 and 16 of App. '976, where the motivation would have been to improve absorbent and mechanical property of resin and simplifies the process of the psoralen removal.

Response to arguments.

Applicants stated that the issue of double patenting will be addressed at a later date should 10/051,976 be otherwise allowable for issuance during the pendency of the present application. Applicants are advised that until claims of the copending and/or the instant application are amended so that the claimed subject matter of the copending and the instant applications is patentably distinct, the rejection under the judicially created doctrine of double patenting will be maintained and no allowable subject matter will be indicated. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or

provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. *See* 37 CFR 1.130(b).

Applicants' arguments with regard to restriction/double-patenting practice are moot, as the instant application is not directly related to application 10/051,976. No statutory bar under 35 U.S.C. 111 exists. Further, it is noted that the double-patenting rejection of instant claims is made over claims of Group II of application 10/051,976, wherein such claims recite both irradiation with light and contacting blood products with resin. It is further noted that claims of Group I of application 10/051,976 do not recite irradiation of psoralen. It is also noted that none of instant claims are rejected over claims of Group I of application 10/051,976. Claims of application 10/051,976 over which the double-patenting rejection is made are withdrawn, but are still pending. Thus, the examiner maintains that the double-patenting rejection is proper.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-5, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph. D. can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Miller
Examiner
Art Unit 1631

MARJORIE A. MORAN
PRIMARY EXAMINER

MM

1/9/04